DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 8 1997

Re: ProstaScint™
Docket No. 97E-0107

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,162,504, filed by Cytogen Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ProstaScint™, the human biologic product claimed by the patent.

The total length of the regulatory review period for ProstaScint™ is 2,561 days. Of this time, 1,906 days occurred during the testing phase and 655 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 26, 1989.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on October 26, 1989.

2. The date the application was initially submitted with respect to the human biologic product under section 351 of the Public Health Service Act: January 13, 1995.

   The applicant claims January 12, 1995, as the date the Product License Application (PLA) for ProstaScint™ (PLA 94-0041) was initially submitted. However, FDA records indicate that PLA 94-0041 was submitted on January 13, 1995.

3. The date the application was approved: October 28, 1996.

   FDA has verified the applicant's claim that PLA 94-0041 was approved on October 28, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: W. Scott McNees
Cytogen Corporation
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Princeton, NJ 08540